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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,014	10/19/2004	Hans-Jurgen Pfannkuche	PN/4-32465A	8464

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
4161	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,014	PFANNKUCHE, HANS-JURGEN	
	Examiner	Art Unit	
	PAUL ZAREK	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _09/12/2005_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _4_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _4_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-3 have been canceled by the Applicant in correspondence of 09/12/2005. Claim 4 is currently pending. This is the first Office Action on the merits of the claim(s).

Priority

2. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) based on an application filed in the United Kingdom on 04/24/2002.

Claim Rejections - 35 USC § 112 (1st Paragraph)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating "GERD, regurgitation, IBS, [and] dyspepsia," does not reasonably provide enablement for "postoperative pain and conditions associated with visceral discomfort/pain." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no description in the specification that specifies or defines what is meant by "postoperative

complaints" or "conditions associated with visceral discomfort/pain." The Examiner reads the claims as broadly as is reasonable and interprets "postoperative complaints" as any condition about which a postoperative patient may complain, which include, but are not limited to, discomfort at the site of incision, nausea or ill-comfort due to anesthesia, and/or the displeasure with the bedside manner of the physician. The Examiner interprets "conditions associated with visceral discomfort/pain" as any condition in which a subject feels pain in the viscera, which Stedman's Medical Dictionary (27th Edition) defines as "[a]n organ of the digestive, respiratory, urogenital and endocrine systems, as well as the spleen, the heart, and great vessels." Therefore, Claim 4 reads on a wide variety of discomfort/pain, including, but not limited to, asthma, heart attacks, and stomach cancer. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07, set forth eight factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (MPEP § 2164.01(a))

A. The breadth of the claim: "postoperative complaints" and "conditions associated with visceral discomfort/pain" could be reasonably interpreted to include varied and disparate conditions (see above);

B. Nature of the invention: method of using positive allosteric $GABA_B$ receptor modulators to treat intestinal or gut-associated pain;

C. The state of the prior art: using $GABA_B$ receptor agonists (i.e. Baclofen) to treat GERD, regurgitation, IBS and dyspepsia. Nothing has been demonstrated regarding the effectiveness of $GABA_B$ receptor agonists on many postoperative

complaints (i.e. dissatisfaction with the bedside manner of the surgeon) or conditions associated with visceral discomfort/pain (i.e. ruptured spleen);

D. Level of one of ordinary skill in the art: physicians and scientists;

E. Level of predictability in the art: $GABA_B$ receptor agonists are known to be an effective treatment for GERD, regurgitation, IBS and dyspepsia. Positive allosteric $GABA_B$ receptor modulators are known to work through similar mechanisms as $GABA_B$ receptor agonists. Little is known about the effect of $GABA_B$ agonism on alleviating complaints about the bedside manner of a surgeon or pain associate with ruptured spleens;

F. Amount of direction provided by the inventor: Applicant discloses support for treating conditions associated with transient lower esophageal sphincter reflux (TLESR), including GERD, regurgitation, IBS, and dyspepsia. Applicant discloses no direction for the treatment of "postoperative complaints" or "conditions associated with visceral discomfort/pain" that are unrelated to TLESR (i.e. dissatisfaction with the beside manner of the surgeon or a rupture spleen, respectively) with positive allosteric $GABA_B$ receptor modulators;

G. Existence of working examples: Applicant discloses support for treating conditions associated with transient lower esophageal sphincter reflux (TLESR), including GERD, regurgitation, IBS, and dyspepsia. Applicant discloses no support that positive allosteric $GABA_B$ receptor modulators can be effectively used to treat "postoperative complaints" or "conditions associated with visceral discomfort/pain" that are unrelated to TLESR (i.e. dissatisfaction with the beside manner of the surgeon or a rupture spleen, respectively) with; and,

H. Quantity or experimentation needed to make or use the invention based on the content of the disclosure: "Postoperative complaints" and "conditions associated with visceral discomfort/pain" may be due to any number of factors which are completely unrelated to TLESR-associated conditions. For example, entirely new fields of research would need to be created to examine the role that positive allosteric $GABA_B$ receptor modulation plays in the interaction between surgeons and patients.

5. Undue experimentation would be required to use the invention as claimed.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "postoperative complaints" in Claim 4 is a relative term which renders the claim indefinite. The term "postoperative complaints" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Applicant has not described what is meant by "postoperative complaints," which may be due to any one of a number of factors. One skilled in the art would not necessarily know for which type(s) of "postoperative complaints" that $GABA_B$ modulation would be appropriate.

9. The term "conditions associated with visceral discomfort/pain" in Claim 4 is a relative term which renders the claim indefinite. The term "conditions associated with visceral discomfort/pain" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Applicant has not described what is meant by "conditions associated with visceral discomfort/pain," which may be due to any one of a number of factors. One skilled in the art would not necessarily know for which type(s) of discomfort or pain $GABA_B$ modulation would be appropriate. As such the metes and bounds of the limitations of Claim 4 are not clear and concise as required by 35 U.S.C. 112, second paragraph.

10. Based on the specification of the instant application, the Examiner interprets "$GABA_B$ receptor modulator" in Claim 4 to mean "positive allosteric modulators of the $GABA_B$ receptor."

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Billstein et al. (International Patent Application, WO 01/41748; published June 14, 2001, hereafter referred to as '748).

13. Claim 4 of the instant application claims a "method for treating GERD, regurgitation, IBS, dyspepsia, postoperative complaints and conditions associated with

visceral discomfort/pain in a subject in need of such treatment, which comprises administering to said subject a therapeutically effective amount of a $GABA_B$ receptor modulator." Billstein et al. claims a "method of treating a patient suffering from altered gastrointestinal motility, sensitivity and/or secretion and/or abdominal disorders comprising administering to the patient a therapeutically effective amount of a pharmaceutical combination according to claim 1 or 2, or of a pharmaceutical composition according to claim 8." Claim 8 of Billstein et al., recites a pharmaceutical composition comprising the combination of: a) "a $5\text{-}HT_4$ receptor agonist or antagonist or a $5\text{-}HT_3$ receptor antagonist;" and b) "$GABA_B$ receptor agonist or modulators." The specification of the '748 application defines gastrointestinal disorders to include IBS, GERD, and dyspepsia (page 1, paragraph 4). Thus, Billstein et al. reads on all the limitations of Claim 4 of the instant application because Billstein et al., teaches the method of treating GERD, IBS, and dyspepsia (which are also "conditions associated with visceral discomfort/pain) with a pharmaceutical composition comprising a $GABA_B$ receptor modulator.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL ZAREK whose telephone number is 571-270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PATRICK NOLAN can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161